SEP 1 8 2006

K060953

510(k) summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is:

User Fee Payment ID. No.: MD6025264-956733

Submitter :

YD Diagnostics
2F, Keukdong A Building, 228-8, Chamsil-Dong Songpa-Gu, Seoul, Korea
Tel.82-31-333-3827, Fax.82-31-339-0176
Contact : Young Nam Park
Date Prepared : March 5, 2004

Contact Person :

Dusic Kwak, Esq.
Kwak & Associates, P. C.
4304 Evergreen Lane, Suite 101
Annandale, Virginia 22003
Tel: 703-658-6347
Fax: 703-658-9807
e-mail: annandalelawfirm@yahoo.com

Device name :

OcculTech Fecal Occult Blood Rapid Test

Common or usual name : Fecal Occult Blood (FOB) Test

Predicate Device :

Instant-View™ Fecal Occult Blood Rapid Test, 510(k) number k021423

Device Description:

The OcculTech Fecal Occult Blood Rapid Test is a colloidal gold enhanced immunoassay for the detection of hemoglobin in human stool. During the assay the specimen stool are absorbed into the sample pad and migrate upwards chromatographically on the membrane by capillary action. The specimen stool

extraction containing hemoglobin forms antigen-antibody complex with monoclonal anti-hemoglobin IgG gold colloid conjugate in the conjugate pad. The mixure migrates to nitrocellulose membrane in the test region where other immobilized monoclonal anti-hemoglobin IgG is present, and then forms a colored sandwich binding (ant-hemoglobin IgG gold colloid-hemoglobin-anti hemoglobin IgG). The OcculTech Fecal Occult Blood Rapid Test is one step test based on the immunochromatography. The test results are visually determined without using any special instrument. It is a simple operation and a number of specimen can be treated in minimal time.

The following types of tests for fecal occult blood (FOB) testing are commercially available Guaiac, Hemoporphyrin and immunochemical. The guaiac test is widely available but lacks in accuracy. The hemoporphyrin test can cause false positive result for patients who have gastric or duodenal ulcers. The immunochemical FOB rapid test is much more sensitive and has been designed to specifically detect low levels of human fecal occult blood.

Intended Use:

The OcculTech Fecal Occult Blood Rapid test is a card type rapid test and an immunochromatography-based *in-vitro* test designed for qualitative detection of fecal occult blood that can be performed in laboratories or physicians offices. It is useful in determining gastrointestinal bleeding found in a number of gastrointestinal disorders (e.g., diverticulitis, colitis, polyps and colorectal cancer). This device is recommended for use in routine physical examinations, when hospital patients are first admitted, hospital monitoring for bleeding in patients, and screening for colorectal cancer or gastrointestinal bleeding from any source.

Statement of how the technology characteristics of the device Compare to the predicate device:

The technology characteristics of the OcculTech Fecal Occult Blood Rapid Test is same as the legally marked predicate device (Instant-View™ Fecal Occult Blood Rapid Test).

Sensitivity and Prozone effect :

In study of 40 stool extraction samples, the OcculTech Fecal Occult Blood Rapid test can detect the human hemoglobin(hHb) at the level close to or higher than 50ng/mL in extraction buffer. No interference from prozone effect was observed when the hHb level reached up to 2000ng hHb/mL, which is equivalent to 2mg hHb/g feces.

Human hemoglobin level performed this study are as following :
0, 37.5, 50, 62.5, 2000ng hHb/mL.

Specificity (cross-reactivity)

In study of cross-reactivity for hemoglobin from other species, both Devices (Occul Tech, Instant-View™) indicated negative test results when tested with the Hb of other species when hHb was absent(Negative solution) and positive test results in all cases when hHb was present(Positive solution, 50ng/mL).

This test results showed that OcculTech Fecal Occult Blood Rapid Test agrees 100% with predicate device.

Hemoglobin of other species used this test are as following :
Horse hemoglobin, Rabbit hemoglobin, Fish hemoglobin, Beef hemoglobin, Chicken Hemoglobin, Goat hemoglobin, Pig hemoglobin, Sheep hemoglobin.

Specificity (Interference)

In study of Interference substances Both Devices (OcculTech, Instant-View™) indicated negative test results when tested with the substances when hHb was absent (Negative solution)and positive test results in all cases when hHb was present(Positive solution, 50ng/mL). Each test was performed as duplicates.

This test results showed that OcculTech Fecal Occult Blood Rapid Test agrees 100% agreed with predicate device.

Interference substances tested are as following :
Horseradish perosidase, Red radish, Raw turnip, Cauliflower, Broccoli, Parsnip, Cantaloupe, Ascorbic acid, Iron, Human Serum Albumin.

Reproducibility and Repeatability

In study of reproducibility and repeatability, the results obtained from the tests performed by the three professionals with diverse education backgrounds and work experiences agreed 98% with expected results(average). The results obtained from the Reference Laboratory agreed 99% with expected results. And OcculTech Fecal Occult Blood Rapid Test agreed 99% with Instant-View™ Fecal Occult Blood Rapid Test.

Stability

- For specimen

The test result showed that specimen can store up to 6 months at 4℃ and 24 months at -20℃.

- For test strip after opening

The test result showed that test strip after opening can store up to 28 days at room temperature.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 18 2006

YD Diagnostics Corporation
c/o Kwak & Associates
4304 Evergreen Lane
Suite 101
Annandale, VA 22003
ATTN: Dusic Kwak

Re: k060953
Trade/Device Name: OcculTech Fecal Occult Blood Rapid Test
Regulation Number: 21 CFR 864.6550
Regulation Name: Occult blood test
Regulatory Class: II
Product Code: KHE
Dated: April 4, 2006
Received: April 6, 2006

Dear Mr. Kwak:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

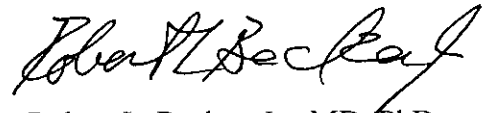
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter

will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150, or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



Robert L. Becker, Jr., MD, PhD
Director
Division of Immunology and Hematology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k060953

Device Name: OcculTech Fecal Occult Blood Rapid Test

Indications For Use:

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Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K060953